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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/025,966 | 12/21/2001 | Steven Rosen | UCAL-230 | 2216 |
| 24353 | 7590 | 10/07/2003 | EXAMINER | |
| BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025 | | | SLOBODYANSKY, ELIZABETH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,966

Applicant(s)

ROSEN ET AL.

Examiner

Elizabeth Slobodyansky

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-22 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a glucosamine-6-sulfatase, classified in class 435, subclass 196.
- II. Claims 4-8, drawn to a polynucleotide encoding glucosamine-6-sulfatase, a vector containing it, a cell transformed with the same, a method of use of said cell and a method of use of said DNA, classified in class 435, subclass 6.
- III. Claim 9, drawn to a monoclonal antibody against glucosamine-6-sulfatase, classified in class 530, subclass 388.1.
- IV. Claims 10 and 11, drawn to a method of identifying an agent that inhibits a sulfatase, classified in class 435, subclass 19.
- V. Claims 12-14, 18 and 19, drawn to methods of treatment of an individual with an agent that inhibits a sulfatase, classified in class 514, subclass 789.
- VI. Claim 15, drawn to a method of treatment of an individual with a sulfatase, classified in class 424, subclass 94.6.

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VII. Claims 16 and 17, drawn to a method of detecting a cancerous cell in a tissue by determining the level of an mRNA, classified in class 435, subclass 6.

VIII. Claims 20-22, drawn to a method of detecting a cancerous cell in a tissue by determining the level of a sulfatase, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct because a protein, a polynucleotide and an antibody are different compounds each with its own chemical structure and function, and they have different utilities. The polynucleotide molecule of invention II is not limited in use for the production of sulfatase of invention I but can be used as a hybridization probe in a method of invention VII and a sulfatase polypeptide of invention I can be obtained by a materially different method such as by the biochemical purification. While a polypeptide of invention I is related to an antibody of invention III as being cognate antigen, the structure of an antibody is unpredictable from the structure of the polypeptide. An agent used in invention V can be used for modulation of function of different proteins and for the production of an antibody, for example.

Inventions (I and IV, VI, VIII) and (II and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

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be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a sulfatase of invention I can be used for the production of an antibody of invention III and in any of methods of inventions IV, VI or VIII. The polynucleotide molecule of invention II can be used for the production of sulfatase in a method of invention II and as a hybridization probe in a method of invention VII.

Inventions IV-VIII are patentably distinct because they are directed to materially different methods. Methods of inventions IV, VII, VIII are *in vitro* methods while a methods of inventions V and VI are *in vivo* methods.

Inventions IV-VIII are patentably distinct because they are directed to materially different methods employing different compounds such as a polypeptide, a polynucleotide and an agent. These methods employ different protocols, chemicals and have different utility.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

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Claims 1-22 are generic to a plurality of disclosed patentably distinct species comprising SEQ ID NOs: 3, 6, 9, 12, 15 and 18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in black ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

October 2, 2003